

Fitment For Flexible Container

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 **[0001]** The present invention relates generally to flexible containers. Particularly, the present invention relates to fitments for sealed, flexible containers. More particularly, the present invention relates to a sealing method for a fitment to a single or multi-layered flexible container intended for long term oxygen stability.

10 2. Description of the Prior Art

[0002] Pouch-type flexible containers have been used for sterile packaging of various foodstuffs, liquids and other degradable material. These flexible containers are typically made from webs of flexible film that are folded and sealed together along the unconnected peripheral sides. A few medical solutions have been sterilely
15 packaged in pouch-type flexible containers as well as solutions used to insure proper performance of various chemical analyzers.

[0003] For example, to insure proper performance of Blood Gas Analyzers, control material is typically run several times per day. This material consists of solutions that have been tonometered to specific values of dissolved oxygen and
20 carbon dioxide concentrations along with specific pH values and electrolyte and metabolic concentrations. For external control samples, the current state of the art is to store the control material in glass ampules. In order to run these controls the

operator must break the ampules and manually introduce the samples into the analyzer, typically at predetermined time intervals, three levels of control per shift, three times per day. This approach is time consuming and requires user intervention.

- 5 **[0004]** A recent trend in the industry is to automate this process by storing the control material on board the analyzer and automatically running the required controls at preset time intervals. This greatly reduces the amount of time required by the operator. One approach for storing the control material on board the analyzer is to package it in flexible containers such as pouches and docking these pouches to
- 10 the analyzer. A disadvantage with this approach is that, typically, the pouch material is not as good of a barrier to gas transport as are the glass ampules used for external controls. Examples of various concerns with use of a flexible container are an increase in oxygen of the control material due to oxygen diffusion through the flexible container material, a reduction in oxygen concentration due to a chemical
- 15 reaction between the control fluid and the flexible container material, etc.

- [0005]** The majority of flexible films used for flexible containers are monolayer PVC films. Recently, a few multiple-layer, extrusion or adhesive laminated films have been developed. These multiple-layer films typically have an inner, solution contacting film layer and an outer barrier layer that can be made of aluminum foil or
- 20 some other barrier material. The inner, solution contacting layer must be substantially inert to the solution while the outer barrier layer must be durable and also compatible with other materials that may contact or be attached to the outside surface. The flexible container or pouch is formed from flat, film material by heat

sealing the edges together and thereby melting the inner plastic layer. These pouches typically require a fitment for accessing the contents of the pouch. For use in blood gas and chemistry analyzers, the pouches require a fitment that docks the pouch to the analyzer and makes the fluid connection. Currently, the fitment is

5 placed at the periphery of the bag between two layers of the bag and the fitment and the inner plastic layer of the flexible container or bag are melted to each other. This requires that the fitment material and the bag material have similar melting points.

This limitation requires that the fitment is typically made of a low melting point plastic, such as polyethylene. A primary disadvantage of the fitment material is that the

10 fitment material typically has a higher oxygen permeability than the film material. In other words, the fitment is a "hole" in the sealed bag. The permeability characteristic of the fitment material is much poorer than the similar characteristic for the laminated film used to make the flexible container. Thus, the fitment is often the weakest part of the barrier characteristics of the flexible container. Another disadvantage is that
15 the heat sealing process tends to damage the barrier layer, which can lead to inconsistent performance.

[0006] U.S. Patent No. 5,514,123 (1996, Adolf et al.) discloses a sterile formed, filled and sealed flexible solution container and a sterile administration port assembly which is attached without interrupting the complete sealing of the hermetically sealed
20 fluid container and which allows for the sterile packaging, storage and delivery of a sterile medical solution without heat degradation or oxygen permeation. Particularly, the flexible container is thermally fused to the saddle flange of the administration port assembly.

[0007] U.S. Patent No. 6,142,341 (2000, Uematsu) discloses a spout assembly comprising a spout and a cap. The spout has a cylindrical outer tube to be placed outside a package and a base to be bonded to the inner surface of the package. The cap is separably connected to an extremity of the cylindrical outer tube coaxially with
5 the cylindrical outer tube in a position in which the cap is pushed into the cylindrical outer tube.

[0008] U.S. Patent No. 6,378,731 (2002, Klabes) discloses a pouring spout for a bag, which comprises a spout, which is inserted into a bag opening. The spout is detachably held in the bag opening by a clamping means, such that it is sealed
10 opposite the bag wall.

[0009] A disadvantage of the prior art is that fitment attachment requires heat sealing of the fitment to the flexible film material at the periphery of the container. This limits the available material that can be used for the fitment to a low melting point plastic. These materials have relatively high oxygen permeability properties.
15 Another disadvantage is the damage induced to the barrier layer during the heat sealing process to the fitment. A further disadvantage of a mechanical clamping seal of certain prior art is that the clamping mechanism and spout must be connected to the flexible material along the periphery of the pouch.

[0010] Therefore, what is needed is a fitment that is made of a low oxygen
20 permeable material for use with flexible containers. What is further needed is a fitment that reduces the damage to the barrier layer of the flexible container when attached. What is also needed is a fitment and flexible container capable of preserving the contents of the flexible container for a longer period of time.

SUMMARY OF THE INVENTION

[0011] It is an object of the present invention to provide a fitment for use with a flexible container that limits the damage to the barrier layer of the flexible container. It

5 is another object of the present invention to provide a fitment for use with a flexible container that has low gas permeability properties. It is a further object of the present invention to provide a fitment for use with a flexible container that does not require attachment along the sealed periphery of the flexible container. It is yet another object of the present invention to provide a fitment for use with a multi-
10 layered, flexible container that increases the shelf life of the contents of the flexible container.

[0012] The present invention achieves these and other objectives by providing a fitment attached to a flexible container using by a mechanical sealing method. The fitment includes at least a lower fitment member and an upper fitment member.

15 Optionally, the fitment may include at least one gasket, but preferably includes a lower fitment gasket and an upper fitment gasket. The lower fitment member includes a lower fitment body having a top surface and a fluid conducting opening. Lower fitment member may optionally include one or more posts extending from the top surface of the lower fitment body. The optional lower fitment gasket is configured
20 with the top surface of the lower fitment member. Where the optional posts are included on the lower fitment member, one or more openings may also be optionally provided in lower fitment gasket and positioned to align with the one or more posts.

[0013] The optional upper fitment gasket is similar to the lower fitment gasket and may also be optionally configured with one or more openings positioned to align with the one or more posts of the lower fitment member. The upper fitment member includes an upper fitment body having an upper member fluid conducting opening in
5 a top surface, preferably a tubular member extending from the top surface and axially aligned with said upper member fluid conducting opening. When the upper fitment member is assembled to the lower fitment member, the upper fitment fluid conducting opening is aligned with the lower fitment fluid conducting opening forming a fluid passageway. The fluid passageway may optionally and preferably include a
10 septum. Where the optional posts are included on the lower fitment member, at least an equal number of post receiving apertures are incorporated into the upper fitment member where the post receiving apertures are positioned to align with the one or more posts of the lower fitment member.

[0014] The lower fitment member optionally includes a recess in the bottom of the
15 lower fitment body. The fluid conducting opening through the lower fitment member is preferably centrally located to align with the upper fitment fluid opening of the upper fitment member.

[0015] The fitment is attached to a flexible film used to make a flexible container/pouch/bag at a position along the film's surface. The position selected
20 preferably includes one or more holes (the number of holes are preferably equal to the number of posts on lower fitment member) through the film that align with the one or more posts of the lower fitment member. To assemble the fitment of the present invention, an optional lower fitment gasket is attached to the lower fitment

member. The flexible film with optional holes is positioned up against the optional lower fitment gasket, or if no gasket is used, up against the top surface of the lower fitment member. An optional upper fitment gasket is positioned against the flexible film opposite the top surface of the lower fitment member, or if no gasket is used, the upper fitment bottom surface is positioned against the flexible film. Upper fitment member preferably has a septum in axial alignment with the upper fitment fluid opening. With the lower fitment member in a fixed position, upper fitment member is subjected to a downward force compressing the optional gaskets and the flexible film forming a fluid tight seal. During compression, the lower fitment member is fused to the upper fitment member using any sealing means known to one of ordinary skill in the art such as, for example, heat staking, etc. Where a lower fitment member having one or more posts is used, the posts are fused to the upper fitment member.

[0016] In an embodiment to enhance the shelf life of the contents of the flexible container, a second or third or more layers of flexible material are used to form bags-within-a-bag. In this embodiment, an additional optional gasket for each additional layer is preferably used to insure a fluid tight seal. Effectively, this embodiment may be considered as a container-within-a-container or a bag-within-a-bag structure.

Between the containers is a quantity of fluid or control material that is similar to the fluid or material to be placed within the flexible container for later use. For example, when the present invention is used with blood gas analyzers, the volume between the inner container and the outer container can either be filled with the same liquid (tonometered to the same gas concentrations) or a gas with similar oxygen and

carbon dioxide concentrations. The inner bag is filled with the control material that will be used by the analyzer.

BRIEF DESCRIPTION OF THE DRAWINGS

5 **[0017]** FIGURE 1 is a perspective view of one embodiment of the present invention showing the individual components in alignment.

[0018] FIGURE 2 is a front view of the embodiment in Fig. 1 showing the placement of the flexible film of the container.

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[0019] FIGURE 2a is a bottom view of the lower fitment member of the present invention.

[0020] FIGURE 3 is a perspective view of another embodiment of the present invention showing the individual components in alignment when multiple layers of flexible film is used.

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[0021] FIGURE 4 is a front view of the embodiment in Fig. 3 showing placement of two layers of flexible film of the container within a container.

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[0022] FIGURE 5 is a front view of a combination of a fitment and a double container.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0023] The preferred embodiment(s) of the present invention are illustrated in

Figs. 1-5. Figure 1 illustrates a perspective view of a fitment **10** of the present

invention. Fitment **10** includes at least a lower fitment member **20**, a lower fitment

5 gasket **30**, an upper fitment gasket **40**, and an upper fitment member **50**. The lower

fitment member **20** includes a lower fitment body **22** having a top surface **24**, a fluid

conducting opening **26** and one or more posts **28** extending from the top surface **24**

of lower fitment body **22**. The lower fitment gasket **30** is configured with openings **32**

positioned to align with the posts **28** and the top surface **24** of the lower fitment

10 member **20**. The upper fitment gasket **40** is similar to lower fitment gasket **30** and is

also configured with openings **42** positioned to align with the posts **28** of the lower

fitment member **20**. The upper fitment member **50** includes an upper fitment body

51 having an upper fitment bottom surface **53** (not shown), an upper fitment fluid

conducting opening or fluid conduit (not shown) in a top surface **54** with preferably a

15 tubular member **52** extending from top surface **54** and post receiving apertures **58**

positioned to align with the posts **28** of the lower fitment member **20**. Septum **56** (not

shown) is seated within the upper fitment body **51** and axially aligned with the tubular

member **52**.

[0024] Turning now to Figure 2, there is illustrated a front view of the embodiment

20 in Fig. 1 with a partial segment of a flexible container material. Figure 2 shows a

flexible container material **70** positioned between lower fitment gasket **30** and upper

fitment gasket **40**. Fitment gaskets **30** and **40** are incorporated to prevent leakage

around posts **28**. Flexible container material **70** preferably includes through holes **72** spatially positioned to align with the posts **28** of lower fitment member **20**. Lower fitment body **22** preferably has a recess **21** (as indicated by the dashed lines and as more clearly shown in Fig. 2a) in the bottom **23**. Recess **21** minimizes the possibility that, as the contents of the flexible container deplete, the flexible material collapses against the exit port and blocks the port preventing the contents from being withdrawn. Septum **56** is positioned within septum recess **55** in upper fitment body **51** in axial alignment with upper fitment fluid opening **57**. It is important to note that the fitment is mechanically sealed to the flexible container material using compression and then heat staking the posts **28** of lower fitment member **20** to upper fitment member **50** while under compression. Because the flexible container material **70** is not heat sealed to the fitment **10**, a low gas permeable material can be used for fitment **10**. In the present invention, fitment **10** is preferably made of an acrylonitrile methyl acrylate copolymer available under the trademark Barex[®] 210 from Barex Resins, Naperville, IL.

[0025] Flexible container material **70** is a flexible film preferably having low gas permeability but is also capable of fusing to itself to create a bag or pouch. This type of flexible film is typically a multi-layered plastic material that includes a barrier layer that is made of aluminum foil or some other barrier material. For the present invention, the flexible film is preferably a barrier film such as, for example, a heavy duty barrier packaging available from PacTech, a division of HAL Baggin, Inc., Rochester, NY, or a product sold under the trademark Escal[™] made by Mitsubishi.

Escal^{lm} barrier film is a polypropylene. The barrier layer is a vacuum-deposited ceramic on a PVA substrate and the inner sealing layer is polyethylene.

[0026] Turning now to Figure 3, there is illustrated another embodiment of the present invention showing the components for a bag-in-a-bag system. For simplicity and clarity, like components are similarly numbered as those illustrated in Figs. 1 and 2. In this embodiment, fitment **10** includes at least a lower fitment member **20**, a lower fitment gasket **30**, a middle gasket **90**, an upper fitment gasket **40**, and an upper fitment member **50**. The structural features of this embodiment are the same as the embodiment shown in Fig. 1 except that an additional middle gasket **90** is included to be positioned between adjacent layers of flexible film material. In fact any number of layers may be used by adding an additional gasket between each film layer. It should be understood by those skilled in the art that an adjustment may be made in the length of posts **28** of lower fitment member **20** in order to accommodate the additional layers and gaskets intended to be used.

[0027] Figure 4 illustrates a front view of the embodiment in Fig. 3 with a partial segment of a first and second flexible container material. Flexible container material **70** is positioned between lower fitment gasket **30** and middle gasket **90**. Flexible container material **75** is positioned between middle gasket **90** and upper fitment gasket **40**. Fitment gaskets **30**, **40** and **90** are incorporated to prevent leakage around posts **28**. Flexible container material **75**, like material **70**, preferably includes through holes **76** spatially positioned to align with the posts **28** of lower fitment member **20**.

[0028] Turning now to Figure 5, there is illustrated the combination of fitment **10** with a bag-within-a-bag container forming a filled and hermetically-sealed container system **100**. Container system **100** includes a first bag container **110** sealed along its periphery **112** and filled with a material **114**, a second bag container **120** sealed
5 along its periphery **122** and filled with a quantity of material **124** that is similar to material **114**, and a fitment **10** attached through the surfaces of first bag container **110** and second bag container **120**. In a blood-gas analyzer, for example, material **114** is a tonometered fluid and material **124** may be the same tonometered fluid or a gas with similar oxygen and carbon dioxide concentrations as that contained within
10 the tonometered fluid **114**.

[0029] Fitment **10** is assembled to flexible container material **70** as previously described and shown. Once the individual components (lower fitment member **20**, lower fitment gasket **30**, material **70**, upper fitment gasket **40**, and upper fitment member **50** with septum **56** installed) are assembled, the fitment **10** and material **70**
15 are sealed by mechanically compressing upper fitment member **50** to lower fitment member **20**. A pneumatic cylinder is preferably used to compress the gaskets **30** and **40** and the material **70** making a fluid tight seal. While under compression, posts **28** of lower fitment member **20** are fused to upper fitment member **50** (as shown by reference numeral **130** in Fig. 5). Although the preferred method uses
20 heat to stake the posts **28** to upper fitment member **50**, ultrasonic or other sealing methods can also be used, all as is generally known to those skilled in the art.

[0030] Where a multiple bag system is assembled, additional gaskets are placed between layers of flexible film material and the same sealing process is performed. Once fitment **10** is attached to one or more flexible film materials, the flexible films are folded onto themselves and a peripheral seal is made along two of the three
5 sides. The nearly complete bag or pouch is then filled with the intended solution or material and then the third and last side is peripherally sealed. In a double bag system, the inner bag is filled and sealed first, followed by the filling and sealing of the outer bag.

[0031] Although the preferred embodiments of the present invention have been
10 described herein, the above description is merely illustrative. Further modification of the invention herein disclosed will occur to those skilled in the respective arts and all such modifications are deemed to be within the scope of the invention as defined by the appended claims.